



# **Informed Consent: Recent Developments in Legal and Ethical Requirements for Data Collection and Use**

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# Consent to Research: Background

- Research with human subjects is usually predicated on obtaining informed consent to participation for two reasons
  - Allows subjects to avoid unwanted risks
  - Permits subjects to control use of their information/biological samples
- Hence, considerable information usually provided to subjects prior to obtaining consent



# Required Elements of Disclosure

- (1) Purposes and procedures
- (2) Reasonably foreseeable risks or discomforts;
- (3) Reasonably expected benefits;
- (4) Appropriate alternatives;
- (5) Confidentiality of records;
- (6) Compensation and treatment for injury;
- (7) Contact for answers to questions;
- (8) Participation is voluntary.



# Privacy Rules Also Reflect This Approach

- HIPAA regulations require the following information in an authorization:
  - (i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
  - (ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
  - (iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
  - (iv) A description of each purpose of the requested use or disclosure.
  - (v) An expiration date or an expiration event



## Biobanking Research: The Dilemma

- When samples are collected for biobanking, the investigators, nature, purpose, and methods of future research may not be known
- Recontacting a large number of sample donors for consent may not be feasible (and may lead to bias)
- Hence, the usual approach to informed consent may be problematic



# Identifiability Conundrum

- If samples rendered non-identifiable, may be exempt from consent/HIPAA requirements—but may also lose much of their research value
- Moreover, even if risks eliminated by anonymizing data, subjects' interest in controlling use of samples donated is not **protected** (Eriksson & Helgesson, Eur J Hum Gen 13:1071-6, 2005)



# Is Waiver of Consent the Solution?

— Federal research regulations permit IRBs to waive consent requirements when:

- (1) The research involves no more than minimal risk  
to the subjects;
- (2) The waiver or alteration will not adversely affect  
the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.



# HIPAA Also Has Exceptions

- Authorization requirement can be waived when:
  - (A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals,
  - (B) The research could not practicably be conducted without the waiver or alteration; and
  - (C) The research could not practicably be conducted without access to and use of the protected health information.



# Waiver of Consent Not the Whole Answer

- When samples collected prospectively for research purposes, it may not be “impracticable” to obtain consent—so waiver provisions may not apply
- Thus, we need to ask: “What kind of consent practices should be implemented for biobanking studies, so that the samples can be used for future research?”



## Possibility 1: Standard Consent

- Consent obtained for biobanking *per se*
- When subsequent studies performed, sample donors are asked to give specific consent to each study



# Advantages/Disadvantages

## — Advantage:

- Allows maximum decisional control

## — Disadvantages:

- Cost
- Sample attrition
- Research may not be feasible if standard consent process required



## Possibility 2: Consent to Disease-Specific Research

- At time of sample donation, subjects asked to provide consent to research on specific disease or class of diseases (or conditions) that is focus of study (e.g., depression, anti-social behavior, suicidality), without requiring standard consent to future studies (Spain)

(Da Rocha & Seoane, *Bioethics* 22:440-7, 2008)



# Advantages/Disadvantages

## — Advantages:

- Substantial decisional control retained—although investigators, specific purpose and special risks unknown

## — Disadvantages:

- Researchers can't always foresee uses of data—approach would preclude studies of related conditions or unforeseen opportunities to explore new areas
- Scope of consent will need to be documented and monitored
- Consent and HIPAA waivers probably needed, but may be easier to justify (Wendler, Arch Int Med 166:1449-552, 2006)



## Possibility 3: Consent to Behavioral/Biomedical Research

- At time of sample donation, subjects asked to provide consent to behavioral/biomedical research in general, with no further restrictions (e.g., samples collected in schizophrenia study could be used by cancer researchers) (Hansson et al, Lancet Oncol 7:266-9, 2006)
- Opt-out for specific uses could be permitted (Helgesson et al, Nature Biotech 25:973-5, 2007)



# Advantages/Disadvantages

## — Advantages:

- Nearly complete flexibility for researchers
- Allows subjects maximum scope for altruism

## — Disadvantages:

- Little specificity to consent
- Ability to avoid risks, exercise autonomy limited
- Consent/HIPAA waivers arguably somewhat harder to justify



## Possibility 4: Consent to All Research Uses

- At time of sample donation, subjects asked to provide consent to use in any IRB-approved research project (e.g., commercial product development, tracing migration patterns, refining forensic identification techniques)




# Advantages/Disadvantages

## — Advantages:

- Maximum flexibility for researchers

## — Disadvantages:

- Minimal decisional control for subjects
- No ability to avoid risks/unwanted outcomes
- Consent/HIPAA waivers may be difficult to justify
- May not be optimal use of samples



## Additional Problem: Nature of Information to be Linked Unknown

- In any approach other than standard consent, subjects may be agreeing to subsequent release of medical information—without knowing what that information is.
- E.g., after giving broad consent, subject may be infected with HIV, develop cancer, have an abortion—information that the subject may consider sensitive and be reluctant to release.



## What is the Status Quo?

- Investigators and IRBs are reported to vary considerably in how consent for future studies is structured (and HIPAA is major consideration)
- The bioethics literature suggests that no clear consensus has emerged among scholars either, though general agreement that broader approach than standard consent is needed



# What Do Potential Subjects Want?

- Empirical literature suggests that most people are willing to grant consent for genetic studies (Wendler, *BMJ* 332:544-7, 2006)
- However, many people want to be asked specifically for each study or type of study (Shickle, *Stud Hist Philos Biol BioMed Sci* 37:503-19, 2006)
- And it's unclear how carefully thought through their responses are, and whether they would be different with more information or time for thought



## How Can the Dilemma Be Resolved?

- All approaches involve trade-offs—the question is where the balance will be struck
- Stake-holders need to reach consensus on proper balance of interests/concerns
- Necessary regulatory adjustments can then be undertaken